DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31,2014

Adin Dental Implant Systems Limited
Ms. Iman Khorshid
VP Regulatory Affairs
Industrial Zone Alon Tavor
POB 1128 Afula Elit, 1811101
ISRAEL

Re: K140293
Trade/Device Name: Touareg NP CloseFit™ Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 16, 2014
Received: September 26, 2014

Dear Ms. Khorshid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 010- Indication For Use Statement

An Indication for Use Statement for the Touareg NP CloseFit™ Dental Implants System is provided below.

510(k) Number (if known): K140293

Device Name: Touareg NP CloseFit™ Dental Implants System

Indications for Use:

Intended use for Touareg NP CloseFit™ Dental Implant System:

- To replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla.
- For single-stage or two-stage procedures.
- For immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant maybe immediately loaded when good primary stability is achieved and the functional load is appropriate.
- The **Touareg NP CloseFit™** Dental Implant shall only be used to replace maxillary lateral incisors and mandibular lateral and central incisors.
- The **Trans Mucosal Abutment (TMA)** is indicated for multiple-unit, screw-retained restorations, and may be used in combination with an implant level framework design.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE

Prescription Use ✓____ AND/OR Over-The-Counter Use_

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

OF NEEDED)

Section 003- 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92
And according with Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.

Submitter Information

ADIN DENTAL IMPLANT SYSTEMS LTD
Industrial Zone Alon Tavor
POB 1128 Afula Elit, 1811101, Israel
Tel: (+972)-4-9116162, Cell :(+972)-548-070-138, Fax: (+972) 4-6426733
iman@adin-implants.com
Establishment Reg. Number: 3007518363

Submission contact person:

Iman Khorshid
VP Regulatory Affairs
Tel: (+972)-4-9116162, Cell :(+972)-548-070-138, Fax: (+972) 4-6426733
iman@adin-implants.com

Date of Submission: 21-

January-2014 **Device**

Classification

Trade/Proprietary Device Name:	Touareg NP CloseFit™ Dental Implant
Common name:	Endosseous Dental Implant 21 CFR 872.3640
Product Code:	DZE (subsequent code NHA)
Classification Name:	Endosseous Dental Implant
Classification Regulation:	21 CFR §872.3640
Classification Panel:	Dental Devices
Regulatory Class:	II

Identification of Primary Legally Marketed Predicate Devices

1. ADIN Dental Implant Systems, Endosseous Dental Implant cleared under K081751, (product code DZE, Regulation No. 872.3640).

2. Asstra Tech AB OsseoSpeed™ Narrow Endosseous Dental Implant cleared under K080396 (product code DZE, Regulation No. 872.3640).

Device Description and function

Adin Touareg NP CloseFit™ dental implants are intended to be used as a replacement for missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla.

Touareg NP (Narrow-Platform) CloseFit™ Dental Implants consists of root form dental implants of various lengths and diameters and associated abutment systems, which provide the clinician with cement retained, screw retained and overdenture-type restorative options.

Dental implants are surgically inserted into the upper and/or lower jawbone and are left to heal (osseointegrate) with the bone for a period of up to six months. Upon healing and integration with the bone, the cover screw or healing abutment (if used) is removed, impressions are

taken, and either a transmucosal abutment (which will later be attached to a custom prosthesis) or a healing abutment is attached to the implant. The soft tissues are allowed to heal around

the abutment forming the soft tissues to the contours of the abutment "emergence" profiling. The implant becomes the artificial root structure for a prosthetic tooth or as an abutment structure for bridge work and/or denture retention. Touareg™-NP Dental Implants are available in diameter of 3.0mm with lengths of **8, 10, 11.5, 13,** and **16** mm. The implants and abutments are made from Ti-Al-V alloy which meets ASTM F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications).

Flat connection abutments

Abutments with flat connection for screw retained restoration. Cement retained abutments

These abutments are providing support to prosthetic restoration. The abutments are intended for cemented restorations. The abutment screw intends for securing the abutment to endosseous implant.

Healing Abutments

Healing abutments of specific diameters and shapes are fixated on the implants to displace the gingiva from the space above the implant during the Implant healing time and serve for proper gingiva shaping. They are available in diameters of 3.0 and 4.5mm.

Ball Attachment

Ball abutments are used for implant-retained mucosa-supported restorations, such as dentures.

The device is a prescription use, labeled "Rx only", the device is qualifies for exemption per 21 CFR 801 Subpart D.

The system includes accessories :laboratory analogs, impression copings, drivers for implants insertion (Class 1exempt, not a subject of this submission) intended to facilitate the preparation of prosthetic restorations.

Additional description of specific items

The submission contains drawings of abutments compatible with 3.0mm diameter implant.

- The difference between the NP tapered cover screw (**NP-0073**) and the NP implant cover screw (***NP-0002***) is: ***NP-0002*** is covering the outer diameter of the implant and **NP-0073** is covering only the opening of the implant.
- The use of the NP Flat Connection Abutments (**NP-0030** – **NP-0031**) is: these are transmucosal abutments for retaining screw restoration.
- The use of the NP Locator Abutments 2-6mm (for example, **NP-0052**) is for "locator" attachment for Overdenture.
- The use of the NP-Angled Trans Mucosal Abutments (**NP-0035 - NP-0038**) is for: Correct angulations of dental implants, it is for the multi-unit, screw retained restorations. Used to elevate seating platform of restoration when restoration to implant level not practical.

Intended use for Touareg NP (Narrow-Platform) CloseFit™ Dental Implant system

The implants and the TMA abutments are intended to be used to:

- Replacement for missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla.
- For single-stage or two-stage procedures.
- For immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations, when a one-stage surgical approach is applied, the implant maybe immediately loaded when good primary stability is achieved, and the functional load is appropriate.
- The Touareg NP CloseFit™ Dental Implant shall only be used to replace Maxillary lateral incisors and mandibular lateral and central incisors.
- The Trans Mucosal Abutment System (TMA) is indicated for multiple-unit, screw-retained restorations, and may be used in combination with an implant level framework design.

Principle of Operation

Each Touareg NP CloseFit™ Dental Implant System has a unique design characteristic for matching implants, abutments and prosthetics once assembled.

When a one-stage surgical approach is applied, the implant maybe immediately loaded when good primary stability is achieved and the functional load is appropriate. The Touareg NP CloseFit™ Dental Implant system shall only be used to replace maxillary lateral incisors and mandibular Lateral and central incisors.

Performance Standards

The performance standards which were utilized for demonstrating potential equivalence in this submission were: ISO 14801, ISO 11137-1, ISO 11137-2, ISO 11137-3, ISO 11737-1, ISO 11737-2, ISO 11138-1, ISO 11138-3, ISO 14644-1, ISO 14644-3, ISO 14644-4, ISO 14971,ISO 14161, ISO 10993-1, ASTM F136-12,ASTM F2338, AAMI ST79, AAMI TIR33, USP 71, USP 85, USP161, under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Guidance

Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff

Comparison to the predicate device:

The Touareg NP CloseFit™ Dental Implants are similar in design to the Touareg Dental Implant cleared under Adin Dental Implant System, K081751. The predicate internal connection was changed to internal hex (hexagonal) Morse tapered connection. In addition, dental implant name was changed from Touareg Dental Implants to the Touareg NP CloseFit™ Dental Implants to extend Touareg Implants family's product line, and surface treatment name was changed to OsseoFix™ due to marketing reasons only. In addition, its indications were extended (please see comparison table, in the Indication for use info).

Comparison Table for Dental Implant System:

Characteristic	Subject Dental Implant System	Predicate Dental Implant System	Predicate Dental Implant System
510(k)		K080396	K081751
Manufacturer	Adin Dental Implant Systems	ASTRA TECH AB	Adin Dental Implants System
Item	Touareg NP CloseFit™ Dental Implant and abutments	OsseoSpeed™ Narrow	Dental Implant System
Indication for use	•Replacement for missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. •For single-stage or two-stage procedures. •For immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations, when a one-stage surgical approach is applied, the implant maybe immediately	•To replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. •The device may be used equally well in a single stage or two-stage surgical procedure. •For immediate implantation in	• Dental Implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. •The Dental Implants may be immediately

Characteristic	Subject Dental Implant System	Predicate Dental Implant System	Predicate Dental Implant System
	loaded when good primary stability is achieved, and the functional load is appropriate. •The Touareg NP CloseFit™ Dental Implant shall only be used to replace Maxillary lateral incisors and mandibular lateral and central incisors. •The Trans Mucosal Abutment System (TMA) is indicated for multiple-unit, screw-retained restorations, and may be used in combination with an implant level framework design.	extraction sites or implantation in partially healed or completely healed alveolar ridge situations. •When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate. • The OsseoSpeed Narrow product line shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors.	loaded when good primary stability is achieved and with appropriate occlusal loading
Performance specification	The Implants were subjected to fatigue testing.	The Implants were subjected to analysis of mechanical strength.	The Implants were subjected to analysis of mechanical strength.
Summary of the technological characteristics	The implants are Surgically implanted in partially healed or completely healed alveolar ridge situations When a one- stage surgical approach is applied, the implant maybe immediately loaded when	Immediate loading of single tooth restorations may not be appropriate in such situations.	The implants are Surgically inserted into the upper and/or lower jawbone and are left to heal (osseointegrate)

Characteristic	Subject Dental Implant System	Predicate Dental Implant System	Predicate Dental Implant System
	good primary stability is achieved and the functional load is appropriate		with the bone for a period of up to six months
Angulations of dental system	17, 30	Not known	17
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Diameter	3.0mm	3.0mm	
Manufacturing technology	Machining	Machining	Machining

Packaging/Labeling/Product Information

Advertising material to be used for promotion of the Touareg NP CloseFit™ Dental Implants will be consistent with the indications for use and other materials shown herein.

All materials, suppliers, processing, packaging methods remain the same as those utilized for the predicate (K081751). Touareg NP CloseFit™ Dental Implants are packaged in a radiation sterilizable package. Sterilization is accomplished by means of Co^{60} gamma irradiation.

Sterilization is validated by the bioburden method. The sterility assurance level (SAL) that Adin Dental Implant Systems Ltd. intends to meet for the Touareg NP CloseFit™ Dental Implants is 10^{-6}. The device is not represented to be "pyrogen-free".

Abutments and instruments will be packaged non-sterile in plastic bags.

Safety & Effectiveness

The intended use of the submitted modified Toureg NP CloseFit™ Dental Implant System is identical to the legally marked devices Adin Dental Implants System - K081751

Similarity of intended use and technological features demonstrated, therefore, the risks and benefits are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of modified Touareg NP CloseFit™ Dental Implants.

Substantial Equivalence Statement:

Adin Dental Implant Systems Ltd. demonstrated that, for the purposes of FDA's regulation of medical devices, the Touareg NP CloseFit™ Dental Implant system is substantially equivalent in indications, design and functional features to predicate devices.

Brief Discussion and conclusions drawn from the Non-Clinical Tests Submitted

For a determination of substantial equivalence, the following analysis and bench performance test was performed on Subject Devices and Predicate Devices:

- Touareg NP CloseFit™ Dental Implant System was analyzed to identify worst-case test samples. These worst-case test samples (rational for choosing the Worst case is at Section 18) were subject to fatigue testing in accordance with the FDA guidance Class II Special Controls Guidance Document" Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" and ISO 14801:2007 "Dentistry-Implants-Dynamic fatigue test for Endosseous dental implants". The test was done with angled abutments to demonstrate the design changes did not change the fatigue properties. Fatigue testing also demonstrated that this system meets its predefined acceptance criteria and performs in accordance with its intended use. The fatigue properties of the new design are similar to those of the predicate device. The testing represent that the implants and abutments are substantially equivalent to the identified predicates.
- Further, NP CloseFit™ Dental Implant System also underwent extensive validation activities for cleaning, packaging, shelf-life and sterilization in accordance with Guidance for industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments, and all applicable recognized FDA consensus standards for dental implants, including but not limited to, ISO 11137-1, Sterilization of health care products -- Radiation- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. In addition, NP CloseFit™ Dental
  abutments also underwent extensive validation activities for moist heat sterilization validation for achieving a Sterility Assurance Level of 10^{-6} (according to the FDA consensus standards) by using the parameters: Moist-Heat Sterilization at gravity fed autoclave 132 C° For 15 minutes exposure time, 20 minutes drying time, using the Overkill method. The sterilization validation was made in accordance with applicable recognized FDA consensus standards for dental implants, including but not limited to ISO 17665-1:2006 Sterilization of health care products - Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices and ISO 17665-2:2009 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1.
- Results of risk analysis, case studies, sterilization validation, and packaging testing have demonstrated that Touareg NP CloseFit™ Dental Implant System equivalent to the predicate device implants tested.